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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,897	03/24/2004	Rong Xiang	TSRI 874.1	6550

7590 02/04/2009

OLSON & HIERL, LTD.
36th Floor
20 North Wacker Drive
Chicago, IL 60606

EXAMINER	
SHEN, WU CHENG WINSTON	
ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
02/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/807,897	**Applicant(s)** XIANG ET AL.	
	Examiner WU-CHENG Winston SHEN	**Art Unit** 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 January 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,26,28 and 53*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632

Continuation of 3. NOTE: Claim 1 has been proposed to be amended to change the scope of the invention in terms of specific type of immune response induced by the recited DNA vaccine. The proposed amendments of claim 1 adds the limitation "wherein the DNA vaccine induces a cytotoxic T-lymphocyte immune response against tumor cells when orally administered to a patient". This added limitation renders the claims more narrow in scope and shift the novelty of the invention toward the induction of a cytotoxic T-lymphocyte immune response by the recited DNA vaccine, and by a specific administration route, and thereby raise new issues that would require further consideration and/or search for prior arts.

Continuation of 11. does NOT place the application in condition for allowance because:

(i) Applicant's arguments have failed to overcome the rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Rovero et al. (Rovero et al. Insertion of the DNA for the 163-171 peptide of IL1beta enables a DNA vaccine encoding p185 (neu) to inhibit mammary carcinogenesis in Her-2/neu transgenic BALB/c mice. Gene Ther. 8(6): 447-52, 2001) in view of Gordan et al. (Gordan et al. Universal tumor antigens as targets for immunotherapy, Cytotherapy, 4(4):317-27, 2002), Nagira et al. (Nagira et al., A lymphocyte-specific CC chemokine, secondary lymphoid tissue chemokine (SLC), is a highly efficient chemoattractant for B cells and activated T cells. Eur J Immunol. 28(5):1516-23, 1998), and Lu et al. (US 5,733,760, issued 03/31/1998) because Applicant's arguments rely on the proposed claim amendments, which have not been entered. The rejection is maintained of the record.

Applicant's arguments pertaining to unexpected results of significant upregulation of CD8 T-cells that express CD25, CD28 and CD69 elicited by the claimed vaccine (See page 6 of Applicant's reply filed on 01/22/2009) have been fully considered and found not persuasive because the proposed amendments "wherein the DNA vaccine induces a cytotoxic T-lymphocyte immune response against tumor cells when orally administered to a patient" relevant to the arguments have not been entered. Furthermore, Applicant's arguments that improved efficacy of vaccine by combining DNA encoding survivin and CCL21 compared to DNA encoding survivin or DNA encoding CCL21 alone (See page 7 of Applicant's reply filed on 01/22/2009) have been fully considered and found not persuasive because (1) such a comparison is not required by the claim and (2) Nagira et al. teaches that CCL21/SLC is a highly efficient chemoattractant for B cells and activated T cells, thereby enhacing both B cell and T cell mediated immune responses.

(ii) Applicant's arguments have failed to overcome the rejection of claim 26 under 35 U.S.C. 103(a) as being unpatentable over Rovero et al. (Rovero et al. Insertion of the DNA for the 163-171 peptide of IL1beta enables a DNA vaccine encoding p185 (neu) to inhibit mammary carcinogenesis in Her-2/neu transgenic BALB/c mice. Gene Ther. 8(6): 447-52, 2001) in view of Gordan et al. (Gordan et al. Universal tumor antigens as targets for immunotherapy, Cytotherapy, 4(4):317-27, 2002), Nagira et al. (Nigira et al., A lymphocyte-specific CC chemokine, secondary lymphoid tissue chemokine (SLC), is a highly efficient chemoattractant for B cells and activated T cells. Eur J Immunol. 28(5):1516-23, 1998), Lu et al. (US 5,733,760, issued 03/31/1998) as applied to claim 1 above, and further in view of Bennett et al. (Bennett et al. WO200157059-A1 and U.S. Patent No. 6,335,194, SEQ ID No: 10, columns 27, 53-55; this reference has been provided in the Non-Final office action mailed on 12/13/2006) because Applicant's arguments rely on the proposed claim amendments, which have not been entered. The rejection is maintained of the record.

(iii) Applicant's arguments have failed to overcome the rejection of claim 28 under 35 U.S.C. 103(a) as being unpatentable over Rovero et al. (Rovero et al. Insertion of the DNA for the 163-171 peptide of IL1beta enables a DNA vaccine encoding p185 (neu) to inhibit mammary carcinogenesis in Her-2/neu transgenic BALB/c mice. Gene Ther. 8(6): 447-52, 2001) in view of Gordan et al. (Gordan et al. Universal tumor antigens as targets for immunotherapy, Cytotherapy, 4(4):317-27, 2002), Nagira et al. (Nigira et al., A lymphocyte-specific CC chemokine, secondary lymphoid tissue chemokine (SLC), is a highly efficient chemoattractant for B cells and activated T cells. Eur J Immunol. 28(5):1516-23, 1998), Lu et al. (US 5,733,760, issued 03/31/1998) as applied to claim 1 above, and further in view of Tanabe et al. (Tanabe et al., direct submission, submitted to Genetics Institute, 87 Cambridge Park Drive, Cambridge, MA 02140, USA, on 03-JUN-1997, direct submission of DNA sequences of CCL21; this reference has been provided in the Non-Final office action mailed on 12/13/2006) because Applicant's arguments rely on the proposed claim amendments, which have not been entered. The rejection is maintained of the record.

(iv) Applicant's arguments have failed to overcome the rejection of claim 53 under 35 U.S.C. 103(a) as being unpatentable over Rovero et al. (Rovero et al. Insertion of the DNA for the 163-171 peptide of IL1beta enables a DNA vaccine encoding p185 (neu) to inhibit mammary carcinogenesis in Her-2/neu transgenic BALB/c mice. Gene Ther. 8(6): 447-52, 2001) in view of Gordan et al. (Gordan et al. Universal tumor antigens as targets for immunotherapy, Cytotherapy, 4(4):317-27, 2002), Nagira et al. (Nigira et al., A lymphocyte-specific CC chemokine, secondary lymphoid tissue chemokine (SLC), is a highly efficient chemoattractant for B cells and activated T cells. Eur J Immunol. 28(5):1516-23, 1998), Lu et al. (US 5,733,760, issued 03/31/1998) as applied to claim 1 above, and further in view of Bennett et al. (Bennett et al. WO200157059-A1 and U.S. Patent No. 6,335,194, SEQ ID No: 10, columns 27, 53-55; this reference has been provided in the Non-Final office action mailed on 12/13/2006), and Tanabe et al. (Tanabe et al., direct submission, submitted to Genetics Institute, 87 Cambridge Park Drive, Cambridge, MA 02140, USA, on 03-JUN-1997, direct submission of DNA sequences of CCL21; this reference has been provided in the Non-Final office action mailed on 12/13/2006) because Applicant's arguments rely on the proposed claim amendments, which have not been entered. The rejection is maintained of the record.